

Translation

PATENT COOPERATION TREATY

PCT/JP2003/007837



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 663857	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/007837	International filing date (day/month/year) 20 June 2003 (20.06.2003)	Priority date (day/month/year) 30 September 2002 (30.09.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/5575, 31/4166, 45/00, C07D 233/78, A61P 1/14, 3/04		
Applicant SHIONOGI & CO., LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 20 November 2003 (20.11.2003)	Date of completion of this report 21 April 2004 (21.04.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-16

because:

☒ the said international application, or the said claims Nos. 9-16
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 9 to 16

The inventions set forth in claims 9 to 16 correspond to
"methods for the treatment of the human body by therapy" (PCT
Rule 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8, 17-24	YES
	Claims		NO
Inventive step (IS)	Claims	1-8, 17-24	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8, 17-24	YES
	Claims		NO

2. Citations and explanations

The following documents are cited in the international search report.

Document 1: Marc K. HELLERSTEIN et al., "Interleukin-1-induced Anorexia in the Rat; Influence of Prostaglandins," J. Clin. Invest., Vol. 84, 1989, pages 228 to 235

Document 2: Akira TERAOKA et al., "Interleukin-1 Induces Slow-Wave Sleep at the Prostaglandin D₂-Sensitive Sleep-Promoting Zone in the Rat Brain," The Journal of Neuroscience, 1998, Vol. 18, No. 16, pages 6599 to 6607

Document 3: WO 98/25919 A1 (Shionogi & Co., Ltd.)

Document 4: EP 284202 B (Wellcome Foundation Ltd.)

Document 1 indicates that IL-1 induces eating disorders, and suggests the possibility that this action of IL-1 is mediated by PGE₂ synthesis.

Meanwhile, document 2 indicates that IL-1 induces slow-wave sleep by mediating the synthesis of prostaglandin in the PGD₂-sensitive sleep-promoting zone, and also indicates that IL-1 and prostaglandins exhibit a common action with respect to the induction of fever,

eating disorders, sleep and the like in several organisms.

In addition, documents 3 and 4 disclose compounds that are the same as the prostaglandin D₂ antagonists set forth in the claims of the present international application.

However, documents 1 to 4 do not indicate or suggest that prostaglandin D₂-related substances regulate food intake.

Such being the case, the inventions set forth in claims 1 to 8 and 17 to 24 of the present international application are novel and involve an inventive step in relation to documents 1 to 4.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 to 3, 9 to 11 and 17 to 19 pertain to a therapeutic agent for eating disorders, which contains a compound defined by a desired property (i.e., "a prostaglandin D₂ agonist activity or a prostaglandin D₂ antagonist activity") as an active component. Despite the fact that the scope of claims 1 to 3, 9 to 11 and 17 to 19 includes any compound that has such a property, only an extremely small portion of the claimed compounds can be considered to be supported by the description in the meaning of PCT Article 6, or to be disclosed therein in the meaning of PCT Article 5.

As a result, it is impossible to specify the scope of the "compound exhibiting a prostaglandin D₂ agonist activity or a prostaglandin D₂ antagonist activity," even with consideration of common technical knowledge at the time the present application was filed. Consequently, claims 1 to 3, 9 to 11 and 17 to 19 fail to meet to the requirement of clarity, as defined in PCT Article 6.